

# Therapy efficacy, compliance and long-term outcome of Auto-bilevel therapy compared to continuous positive airway pressure (CPAP) therapy in obstructive sleep apnoea (OSA) patients

<b>Submission date</b> 29/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/11/2012	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

EAME05AUTOBILEVEL01

## **Study information**

**Scientific Title**

**Acronym**

AUTOBILEVEL

**Study objectives**

We hypothesised that auto-bilevel therapy would be equivalent to fixed continuous positive airway pressure (CPAP) therapy on parameters of objective and subjective compliance and therapeutic effectiveness in patients with moderate to severe obstructive sleep apnoea.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethikkommission of Charite Campus-Mitte gave approval on the 1st March 2006 (ref: EA1/044/08)

**Study design**

Controlled, double-blind randomised study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet.

**Health condition(s) or problem(s) studied**

Obstructive sleep apnoea

**Interventions**

After a CPAP titration night patients will be randomised to three months of either BiPAP auto with Biflex or fixed level CPAP. Patients will be followed up at 1, 4, 8 and 12 weeks.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Treatment and therapeutic efficacy will be measured by polysomnography (PSG) at diagnosis, titration and 12 weeks (end of study).

## **Secondary outcome measures**

1. Objective compliance measured by device memory download at one week and the end of the study
2. Subjective compliance and parameters of wellbeing measured at baseline, 4, 8, 12 weeks
3. Epworth Sleepiness Scale measured at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
4. Pittsburgh Sleep Quality Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
5. Functional Outcomes of Sleep Questionnaire measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
6. Calgary Sleep Apnoea Quality of Life Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
7. 12-item Short Form (SF-12) measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
8. Visual Analogue Scale measured in the morning and evening at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
9. Treatment Satisfaction Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
10. Treatment Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
11. Mask/Interface Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks

## **Overall study start date**

05/06/2006

## **Completion date**

09/06/2007

## **Eligibility**

### **Key inclusion criteria**

1. Apnoea/Hypopnoea Index (AHI) greater than 15/h
2. Aged greater than or equal to 21 years and less than or equal to 65 years, either sex
3. Body mass index (BMI) less than 40 kg/m<sup>2</sup>
4. Able to follow the study protocol
5. Successful CPAP titration

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

32

**Key exclusion criteria**

1. Drug abuse
2. Intake of central relevant drugs, sedatives, or other drugs with impairment of sleep
3. Alcohol abuse; consume more than 30 g/d
4. Participation in other clinical-pharmacological studies up to 4 weeks prior of study begin
5. Psychiatric or neurological diseases resulting in impairment of sleep, therapy or compliance
6. Thyroidal dysfunction
7. Chronic pain syndromes
8. Acute cardiac, pulmonary, and other internal diseases
9. Chronic cardiac, pulmonary and other internal diseases resulting in impairment of sleep
10. Central sleep-related breathing disorders or other disorders resulting in hypoventilation
11. Periodic leg movements (PLM)/restless legs syndrome (RLS)
12. Previous exposure to either CPAP or bilevel therapy

**Date of first enrolment**

05/06/2006

**Date of final enrolment**

09/06/2007

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Center of Sleep Medicine

Berlin

Germany

10117

**Sponsor information**

## Organisation

Respironics International, Inc. (France)

## Sponsor details

20 Rue-Jacques Daguerre

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## Sponsor type

Industry

## Website

<http://www.respironics.com/>

## ROR

<https://ror.org/05jz46060>

# Funder(s)

## Funder type

Industry

## Funder Name

Respironics International, Inc. (France)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2012		Yes	No